BIODELIVERY SCIENCES INTERNATIONAL INC
Form S-3
January 31, 2012
Table of Contents

As filed with the Securities and Exchange Commission on January 31, 2012

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or jurisdiction of incorporation or organization)

35-2089858

(I.R.S. Employer Identification No.)

801 Corporate Center Drive, Suite #210

Raleigh, NC 27607

(919) 582-9050

(Address, including zip code, and telephone number, including area code,

of registrant s principal executive offices)

Mark A. Sirgo, Pharm.D.

801 Corporate Center Drive, Suite 210

Raleigh, NC 27607

(919) 582-9050

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Barry I. Grossman, Esq.

Lawrence A. Rosenbloom, Esq.

Ellenoff Grossman & Schole LLP

150 East 42nd Street

New York, New York 10017

(212) 370-1300

Fax: (212) 370-7889

Approximate date of proposed sale to the public: From time to time, after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.[ ]

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registrations statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. [ ]

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company [X]

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Amount to be Registered(1)**	**Proposed Maximum Aggregate Offering Price per Security(1)**	**Proposed Maximum Aggregate Offering Price(1)**	**Amount of Registration Fee(1)(2)(9)(10)**
Common Stock, par value $0.001 per share(3)				
Preferred Stock, par value $0.001 per share(4)				
Debt Securities				
Warrants(5)				
Rights(6)				
Units(7)				
TOTAL	$40,000,000(8)		$40,000,000	$4,584.00

(1) Pursuant to General Instruction II.D to Form S-3, the Amount to be Registered, Proposed Maximum Aggregate Offering Price per Security and Proposed Maximum Aggregate Offering Price have been omitted for each class of securities that are registered hereby.

(2) The registration fee for the unallocated securities registered hereby has been calculated in accordance with Rule 457(o) under the Securities Act of 1933, as amended, and reflects the maximum offering price of securities that may be issued rather than the principal amount of any securities that may be issued at a discount.

(3) An indeterminate number of shares of common stock of BioDelivery Sciences International, Inc. are covered by this Registration Statement.

(4) An indeterminate number of shares of preferred stock of BioDelivery Sciences International, Inc. are covered by this Registration Statement. Shares of common stock issued upon conversion of the debt securities and the preferred stock will be issued without the payment of additional consideration.

(5) An indeterminate number of warrants of BioDelivery Sciences International, Inc., each representing the right to purchase an indeterminate number of shares of preferred stock or shares of common stock or amount of debt securities, each of which are registered hereby, are covered by this Registration Statement.

(6) Rights evidencing rights to purchase securities of BioDelivery Sciences International, Inc.

(7) Each Unit consists of any combination of two or more of the securities being registered hereby.

(8) Also registered hereby are such additional and indeterminable number of securities as may be issuable due to adjustments for changes resulting from stock dividends, stock splits and similar changes as well as anti-dilution provisions applicable to the warrants.

(9) Pursuant to Rule 415(a)(6) under the Securities Act, the securities registered pursuant to this Registration Statement include $40,000,000.00 of unsold securities previously registered on the registrant s Registration Statement on Form S-3 (Registration No. 333-156839), filed with the Securities and Exchange Commission on January 21, 2009, which we refer to as the Prior Registration Statement. Pursuant to Rule 415(a)(6), the offerings of the unsold securities registered under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of this Registration Statement.

(10) In connection with the registration of the unsold securities on the Prior Registration Statement, the registrant paid a registration fee of $1,572 which will continue to be applied to such unsold securities. Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(o) under the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Preliminary Prospectus **Subject To Completion. dated January 31, 2012**

$40,000,000

Common Stock
Preferred Stock
Debt Securities
Warrants
Rights
Units

BioDelivery Sciences International, Inc. may offer and sell from time to time, in one or more series, any one of the following securities of our company:

common stock;

preferred stock;

secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities;

warrants to purchase our securities

rights to purchase any of the foregoing securities; or

units comprised of, or other combinations of, the foregoing securities.

Each time our securities are offered, we will provide a prospectus supplement containing more specific information about the particular offering and attach it to this prospectus. The prospectus supplements may also add, update or change information contained in this prospectus. **This prospectus may not be used to offer or sell securities without a prospectus supplement which includes a description of the method and terms of this offering.**

Our common stock is traded on the Nasdaq Capital Market under the symbol BDSI. As of January 26, 2012, the aggregate market value of our outstanding common stock held by non-affiliates is approximately $49,981,288, based on 29,561,655 shares of outstanding common stock, of which approximately 24,381,116 shares are held by non-affiliates, and a per share price of $2.05 based on the closing sale price of our common stock on January 26, 2012. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on and includes the date that the registration statement of which this prospectus is a part was first filed with the Securities and Exchange Commission.

Investing in our securities involves a high degree of risk. See the section entitled Risk Factors in the accompanying prospectus supplement and in the documents we incorporate by reference in this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2012.

Table of Contents

TABLE OF CONTENTS

About This Prospectus	-i-
Cautionary Note On Forward Looking Statements	-ii-
Prospectus Summary	1
Risk Factors	6
Use of Proceeds	6
Description of Securities and Securities We May Offer	7
Plan of Distribution	15
Legal Matters	17
Experts	18
Incorporation of Certain Documents by Reference	18
Where You Can Find More Information	20
Disclosure of Commission Position on Indemnification for Securities Law Violations	20

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission utilizing a shelf registration process. Under this shelf registration statement, we may, from time to time, sell any combination of the securities referred to herein in one or more offerings for total gross proceeds of up to $40,000,000. This prospectus provides you with a general description of the securities we may offer.

If required, each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of the securities being offered. The prospectus supplement may add, update or change information contained in this prospectus and may include a discussion of any risk factors or other special considerations that apply to the offered securities. If there is any inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in that prospectus supplement. Before making an investment decision, it is important for you to read and consider the information contained in this prospectus and any prospectus supplement, together with the additional information described under the heading Where You Can Find More Information.

You should rely only upon the information contained in this prospectus and the registration statement of which this prospectus is a part. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it.

We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

You should assume the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date. This prospectus is based on information provided by us and other sources that we believe are reliable. We have summarized certain documents and other information in a manner we believe to be accurate, but we refer you to the actual documents for a more complete understanding of what we discuss in this prospectus. In making an investment decision, you must rely on your own examination of our business and the terms of the offering, including the merits and risks involved.

We obtained statistical data, market data and other industry data and forecasts used throughout, or incorporated by reference in, this prospectus from market research, publicly available information and industry publications. Industry publications generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy and completeness of the information. Similarly, while we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information. We have not sought the consent of the sources to refer to their reports appearing or incorporated by reference in this prospectus.

This prospectus contains, or incorporates by reference, trademarks, tradenames, service marks and service names of BioDelivery Sciences International, Inc. and other companies.

Table of Contents

CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS

Certain statements contained or incorporated by reference in this prospectus, including the documents referred to or incorporated by reference in this prospectus or statements of our management referring to our summarizing the contents of this prospectus, include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and related releases issued by the U.S. Securities and Exchange Commission, or SEC, and within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). We have based these forward-looking statements on our current expectations and projections about future events. Our actual results may differ materially or perhaps significantly from those discussed herein, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, expect, anticipate, intend, estimate, plan, project and c similar expressions. In addition, any statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements included or incorporated by reference in this prospectus or our other filings with the SEC include, but are not necessarily limited to, those relating to:

- our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® drug delivery technology platform and any proposed products, product candidates or marketed products, including our sole approved and marketed product, ONSOLIS®, and our partnered product candidate, BEMA® Buprenorphine;

- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including (i) the timing, status and results of our or our commercial partners filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies and (ii) the heavily regulated industry in which we operate our business generally;

- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates;

- our ability, or the ability of our commercial partners to actually develop, commercialize, manufacture or distribute our products and product candidates;

- our ability to generate commercially viable products and the market acceptance of our BEMA® technology platform and our proposed products and product candidates;

- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;

- our expectations about the potential market sizes and market participation potential for our approved or proposed products;

- the protection and control afforded by our patents or other intellectual property, and any interest patents or other intellectual property that we license, or our or our partners ability to enforce our rights under such owned or licensed patents or other intellectual property;

Table of Contents

- the outcome of ongoing or potential future litigation or other claims or disputes relating to our business, technologies, products or processes;
- our expected revenues (including sales, milestone payment and royalty revenues) from our products or product candidates and any related commercial agreements of ours;
- the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner;
- our ability to retain members of our management team and our employees; and
- competition existing today or that will likely arise in the future.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. Please see Risk Factors in our reports filed with the SEC or in a prospectus supplement related to this prospectus for additional risks which could adversely impact our business and financial performance.

Moreover, new risks regularly emerge and it is not possible for our management to predict or articulate all risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this prospectus are based on information available to us on the date of this prospectus. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout (or incorporated by reference in) this prospectus.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights selected information contained or incorporated by reference in this prospectus. This summary does not contain all of the information you should consider before investing in the securities. Before making an investment decision, you should read the entire prospectus and any supplement hereto carefully, including the risk factors section as well as the financial statements and the notes to the financial statements incorporated herein by reference.

In this prospectus and any amendment or supplement hereto, unless otherwise indicated, the terms BioDelivery Sciences International, Inc. , BDSI , the Company , we , us , and our refer and relate to BioDelivery Sciences International, Inc. and its consolidated subsidiaries.

Overview

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of proven therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. We have developed and are continuing to develop pharmaceutical products aimed principally in the areas of pain management and oncology supportive care. We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002.

In formulating our products and product candidates, we utilize the novel, patent protected and proprietary *BioErodible MucoAdhesive (BEMA®)* drug delivery technology, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek). Our first U.S. Food and Drug Administration (which we refer to as the FDA) approved product, ONSOLIS® (fentanyl buccal soluble film), as well as our pipeline of products candidates, utilize our BEMA® technology.

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we may seek to acquire or license additional drug delivery technologies. Should we gain access to such technologies, we would seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through commercial partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace.

Our current development strategy focuses primarily on our ability to utilize the FDA s 505(b)(2) regulatory process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into our drug delivery technologies. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and expeditious, and have less regulatory approval risk, than other FDA approval approaches.

Our Products

ONSOLIS®

On July 16, 2009, we announced the U.S. approval of our first product, ONSOLIS®, a transmucosal formulation of the narcotic fentanyl utilizing our BEMA® technology. ONSOLIS® is indicated for the treatment of breakthrough pain (i.e., pain that breaks through the effects of other medications being used to control persistent pain) in opioid tolerant patients with cancer. In May 2010, regulatory approval was granted for Canada, and in October 2010, approval was obtained in the European Union through the E.U. s Decentralized Procedure, with Germany acting as the reference member state. In the E.U., ONSOLIS® will be marketed under the trade-name BREAKYL . ONSOLIS® was commercially launched in Canada in 2011 and is expected to launch in the E.U. in 2012.

Table of Contents

Our commercial partner for ONSOLIS® is Meda AB, a leading international specialty pharmaceutical company based in Sweden (which we refer to as Meda). In addition to milestone payments we received and may in the future receive from Meda, we began receiving royalties from Meda on net sales of ONSOLIS® following the product s commercial launch in the U.S. and Canada. We anticipate additional royalty sales following launches in the E.U. in 2012, although our royalty revenue from this product remains below original projections due to certain regulatory conditions in the U.S. discussed below.

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Meda s U.S. subsidiary, Meda Pharmaceuticals, based in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets and sells branded prescription therapeutics. Meda has an experienced, well trained and highly regarded sales force with a focus in specialty therapeutic areas including pain, allergy and central nervous system conditions. Meda has established a track record of successfully commercializing products. Meda has secured access to additional markets through acquisition of European businesses from Valeant Pharmaceuticals International, Inc. (which we refer to as Valeant) and a joint venture with Valeant covering Australia, Mexico and Canada.

In 2010, we secured commercialization rights for ONSOLIS® for the remaining worldwide territories through execution of licensing agreements with Kunwha Pharmaceutical Ltd. for South Korea and TTY Biopharm Ltd. for Taiwan.

Although we have generated licensing-related and other revenue to date, we only began to generate revenue from the commercial sales of an approved product (ONSOLIS®) in late 2009 and such revenue has been minimal to date due to multiple factors, including a highly restrictive Risk Evaluation and Mitigation Strategy (REMS) imposed by the FDA. The lack of approved REMS programs for our direct competitors has resulted in an unlevel playing field, which created an unfavorable selling environment for ONSOLIS®. Furthermore, increasing pressure from payers and the availability of generic competitors have further impacted the market.

In December 2011, the FDA approved a class-wide REMS covering all transmucosal fentanyl products under a single risk management program. The program, which will be referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. We believe that a single risk management program will help to enhance patient safety while limiting the potential administrative burden on prescribers of transmucosal fentanyl products and their patients. This common program also ends the disparity in prescribing requirements for ONSOLIS® compared to other similar products. Based on the FDA s approval of the class-wide REMS, we and Meda will pursue a REMS implementation strategy that will seek to provide the best opportunity for access to ONSOLIS® and support future growth.

BEMA® Buprenorphine

Our next product, currently in development, is BEMA® Buprenorphine, a potential treatment for moderate to severe chronic pain. In December 2009, we announced that the primary efficacy endpoint was achieved in a Phase 2 clinical study evaluating the safety and efficacy of a range of doses of BEMA® Buprenorphine. Completion of this Phase 2 study led to the initiation of a Phase 3 double-blind, randomized, placebo-controlled clinical study which was initiated in the fourth quarter of 2010. On

Table of Contents

September 28, 2011, we announced that the primary endpoint of this Phase 3 study, overall pain intensity difference between BEMA® Buprenorphine and placebo, was not achieved. Despite this result, we believe that the totality of the study results favors the continued development of BEMA® Buprenorphine, including a near statistically significant difference between BEMA® Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). In addition, in this same group of opioid experienced patients, when eliminating those that did not titrate beyond the starting dose, a statistically significant difference between BEMA® Buprenorphine and placebo (p=0.025) was identified in this study.

Furthermore, we believe that our outlook on BEMA® Buprenorphine was validated when, in January 2012, we entered into a license and development agreement with Endo Pharmaceuticals, Inc. (which we refer to as Endo) under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BEMA® Buprenorphine for the treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront payment, which we received in January 2012; (ii) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events; (iii) $55 million in potential sales milestones upon achievement of designated sales levels; and (iv) a tiered, mid- to upper-teen royalty on net sales of BEMA® Buprenorphine in the United States and a mid- to high-single digit royalty on net sales of BEMA® Buprenorphine outside the United States. We expect to use portions of our Endo milestone payments to fund our development obligations under the Endo agreement with respect to BEMA® Buprenorphine.

Pursuant to our agreement with Endo, we are responsible for the completion of all clinical trials regarding BEMA® Buprenorphine necessary to submit a New Drug Application (or NDA) to the FDA in order to obtain approval of BEMA® Buprenorphine in the United States, pursuant to a development plan set forth in the Endo agreement. We are responsible for all development activities through the filing of the NDA in the U.S., while Endo is responsible for the development following the NDA submission as well as the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. In addition, Endo is responsible for all filings (including the NDA filing with the FDA) required in order to obtain regulatory approval of BEMA® Buprenorphine.

BEMA® Buprenorphine/Naloxone

In addition to our proposed use of BEMA® Buprenorphine to treat moderate to severe chronic pain, we believe that the widespread use of buprenorphine for the treatment of opioid dependence presents an additional commercial opportunity for the product, and we are developing a formulation of BEMA® Buprenorphine specifically for the treatment of opioid dependence. The product will combine a high dose of buprenorphine along with an abuse deterrent agent, naloxone. Preliminary pharmacokinetic studies have demonstrated the ability of the BEMA® technology to deliver the high doses of buprenorphine necessary for the treatment of opioid dependence. In March 2011, we announced the positive outcome of a pre-Investigational New Drug (pre-IND) meeting with the FDA on the development program for BEMA® Buprenorphine/Naloxone, at which we confirmed that the 505(b)(2) regulatory pathway will be pursued for the clinical development of BEMA® Buprenorphine/Naloxone. In December 2011, we announced positive results from our confirmatory study for this product which assessed the pharmacokinetics of our BEMA® Buprenorphine/Naloxone formulation compared to Suboxone, an FDA-approved treatment for opioid dependence with annual sales in excess of $1 billion. The results confirm the final formulation for the product and provide the basis for moving forward into the pivotal comparative pharmacokinetic study versus Suboxone, which we expect will take place in 2012.

Table of Contents

ONSOLIS® and our product candidates such as BEMA® Buprenorphine may also have broader indications. When presented with viable commercial opportunities for broader indications of our products, we will consider developing the product for those uses.

We also continue to explore the use of the BEMA® technology with additional pharmaceutical products that may fulfill unmet medical needs, such as in the areas of nausea and vomiting and migraines.

Additional Information

Since inception and through September 30, 2011, we have recorded accumulated losses totaling approximately $91.5 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for our product candidates, our goal will be to augment our current sources of revenue and, as applicable, deferred revenue (principally licensing fees), with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

We have based our estimates of development costs, market size estimates, peak annual sales projections and similar matters described or incorporated by reference in this prospectus on our market research, third party reports and publicly available information which we consider reliable. However, readers are advised that the projected dates for filing and approval of our INDs or NDAs with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding ONSOLIS®, BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone or any other product candidates discussed elsewhere (or incorporated by reference) in this prospectus are merely estimates and subject to many factors, many of which may be beyond our control, which will likely cause us to revise such estimates. Readers are also advised that our projected sales figures do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our management s reasonable judgments given the information available and their previous experiences, although such estimates may not prove to be accurate.

Our principal executive offices are located at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina 27607. Our telephone number is (919) 582-9050.

The Securities We May Offer

We may offer and sell from time to time up to an aggregate of $40,000,000 of any of, or units comprised of, or other combinations of, the following securities:

Common Stock

We may issue shares of our common stock. Holders of common stock are entitled to receive ratably dividends if, as and when dividends are declared from time to time by our board of directors out of funds legally available for that purpose, after payment of dividends required to be paid on outstanding preferred stock or series common stock. Holders of common stock are entitled to one vote per share. Holders of common stock have no cumulative voting rights in the election of directors.

Preferred Stock

We may issue shares of our preferred stock in one or more series. Our board of directors will determine the dividend, voting, conversion and other rights of the series of preferred stock being offered.

Table of Contents

Debt Securities

We may offer debt securities, which may be secured or unsecured, senior, senior subordinated or subordinated, may be guaranteed by our subsidiaries, and may be convertible into shares of our common stock. We may issue debt securities either separately, or together with, upon conversion of or in exchange for other securities. It is likely that the debt securities that we may issue will not be issued under an indenture.

Warrants

We may issue warrants for the purchase of preferred stock or common stock or debt securities of our company. We may issue warrants independently or together with other securities. Warrants sold with other securities as a unit may be attached to or separate from the other securities. To the extent the warrants are publicly-traded, we will issue warrants under one or more warrant agreements between us and a warrant agent that we will name in the applicable prospectus supplement.

Rights

We may issue rights to purchase of preferred stock or common stock or debt securities of our company. We may issue rights independently or together with other securities. Rights sold with other securities as a unit may be attached to or separate from the other securities and may be (but shall not be required to be) publicly-listed securities.

Units

We may also issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security.

Prospectus Supplement

We will describe the terms of any such offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. Such prospectus supplement will contain the following information about the offered securities:

- title and amount;
- offering price, underwriting discounts and commissions or agency fees, and our net proceeds;
- any market listing and trading symbol;
- names of lead or managing underwriters or agents and description of underwriting or agency arrangements; and
- the specific terms of the offered securities.

This prospectus may not be used to offer or sell securities without a prospectus supplement which includes a description of the method and terms of this offering.

Table of Contents

RISK FACTORS

Investing in our securities involves a high degree of risk. The prospectus supplement relating to a particular offering will contain a discussion of risks applicable to an investment in the securities offered. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading Risk Factors in the applicable prospectus supplement together with all of the other information contained in the prospectus supplement or appearing or incorporated by reference in this prospectus.

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from these sales for general corporate purposes including the advancement of our product candidates, and to meet working capital needs. The amounts and timing of the expenditures will depend on numerous factors, such as the timing and progress of our clinical trials and research and development efforts, technological advances and the competitive environment for our drug candidates.

Table of Contents

DESCRIPTION OF SECURITIES AND SECURITIES WE MAY OFFER

General

The following description of our capital stock (which includes a description of securities we may offer pursuant to the registration statement of which this prospectus, as the same may be supplemented, forms a part) does not purport to be complete and is subject to and qualified in its entirety by our certificate of incorporation, as amended, and our amended and restated bylaws and by the applicable provisions of Delaware law.

Our authorized capital stock consists of 75,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of the date of this prospectus, our outstanding capital stock consists of 29,561,655 shares of common stock, $0.001 par value, and no shares of preferred stock. These figures do not include securities that may be issued: (i) pursuant to outstanding warrants to purchase shares of our common stock, (ii) pursuant to our Amended and Restated 2001 Incentive Plan or (iii) pursuant to our 2011 Equity Incentive Plan.

We, directly or through agents, dealers or underwriters designated from time to time, may offer, issue and sell, together or separately, up to $40,000,000 in the aggregate of:

- common stock;
- preferred stock;
- secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities;
- warrants to purchase our securities
- rights to purchase our securities; or
- units comprised of, or other combinations of, the foregoing securities.

We may issue the debt securities as exchangeable for or convertible into shares of common stock, preferred stock or other securities. The preferred stock may also be exchangeable for and/or convertible into shares of common stock, another series of preferred stock or other securities. The debt securities, the preferred stock, the common stock and the warrants are collectively referred to in this prospectus as the securities. When a particular series of securities is offered, a supplement to this prospectus will be delivered with this prospectus, which will set forth the terms of the offering and sale of the offered securities.

Common Stock

As of January 26, 2012, there were 29,577,146 shares of common stock issued and 29,561,655 shares of common stock outstanding, held of record by approximately 136 stockholders. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Subject to preferential rights with respect to any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefore. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and satisfaction of preferential rights of any outstanding preferred stock.

Table of Contents

Our common stock has no preemptive or conversion rights or other subscription rights. There are no sinking fund provisions applicable to the common stock. The outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our certificate of incorporation, as amended, empowers our board of directors, without action by our shareholders, to issue up to 5,000,000 shares of preferred stock from time to time in one or more series, which preferred stock may be offered by this prospectus and supplements thereto. As of January 26, 2012, no shares of preferred stock were designated or outstanding. Our board may fix the rights, preferences, privileges, and restrictions of our authorized but undesignated preferred shares, including:

- dividend rights and preferences over dividends on our common stock or any series of preferred stock;
- the dividend rate (and whether dividends are cumulative);
- conversion rights, if any;
- voting rights;
- rights and terms of redemption (including sinking fund provisions, if any);
- redemption price and liquidation preferences of any wholly unissued series of any preferred stock and the designation thereof of any of them; and
- to increase or decrease the number of shares of any series subsequent to the issue of shares of that series but not below the number of shares then outstanding.

You should refer to the prospectus supplement relating to the series of preferred stock being offered for the specific terms of that series, including:

- the title of the series and the number of shares in the series;
- the price at which the preferred stock will be offered;
- the dividend rate or rates or method of calculating the rates, the dates on which the dividends will be payable, whether or not dividends will be cumulative or noncumulative and, if cumulative, the dates from which dividends on the preferred stock being offered will cumulate;
- the voting rights, if any, of the holders of shares of the preferred stock being offered;

the provisions for a sinking fund, if any, and the provisions for redemption, if applicable, of the preferred stock being offered, including any restrictions on the foregoing as a result of arrearage in the payment of dividends or sinking fund installments;

Table of Contents

the liquidation preference per share;

the terms and conditions, if applicable, upon which the preferred stock being offered will be convertible into our common stock, including the conversion price, or the manner of calculating the conversion price, and the conversion period;

the terms and conditions, if applicable, upon which the preferred stock being offered will be exchangeable for debt securities, including the exchange price, or the manner of calculating the exchange price, and the exchange period;

any listing of the preferred stock being offered on any securities exchange;

a discussion of any material federal income tax considerations applicable to the preferred stock being offered;

any preemptive rights;

the relative ranking and preferences of the preferred stock being offered as to dividend rights and rights upon liquidation, dissolution or the winding up of our affairs;

any limitations on the issuance of any class or series of preferred stock ranking senior or equal to the series of preferred stock being offered as to dividend rights and rights upon liquidation, dissolution or the winding up of our affairs; and

any additional rights, preferences, qualifications, limitations and restrictions of the series.

Upon issuance, the shares of preferred stock will be fully paid and nonassessable, which means that its holders will have paid their purchase price in full and we may not require them to pay additional funds.

Any preferred stock terms selected by our board of directors could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and power, including voting rights, of the holders of our common stock without any further vote or action by the stockholders. The rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued by us in the future. The issuance of preferred stock could also have the effect of delaying or preventing a change in control of our company or make removal of management more difficult.

Warrants

We may issue warrants for the purchase of our common stock, preferred stock or debt securities or any combination thereof. Warrants may be issued independently or together with our common stock, preferred stock or debt securities and may be attached to or separate from any offered securities. To the extent warrants that we issue are to be publicly-traded, each series of such warrants will be issued under a separate warrant agreement to be entered into between us and a bank or trust company, as warrant agent. The warrant agent will act solely as our agent in connection with such warrants. The warrant agent will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. This summary of certain provisions of the warrants is not complete. For the terms of a particular series of warrants, you should refer to the prospectus supplement for that series of warrants and the warrant agreement for that particular series.

Table of Contents

Debt Securities

As used in this prospectus, the term debt securities means the debentures, notes, bonds and other evidences of indebtedness that we may issue from time to time. The debt securities will either be senior debt securities, senior subordinated debt or subordinated debt securities. We may also issue convertible debt securities. Debt securities issued under an indenture (which we refer to herein as an Indenture) will be indenture entered into between us and a trustee to be named therein. It is likely that convertible debt securities will not be issued under an Indenture.

The Indenture or forms of Indentures, if any, will be filed as exhibits to the registration statement of which this prospectus is a part. The statements and descriptions in this prospectus or in any prospectus supplement regarding provisions of the Indentures and debt securities are summaries thereof, do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of the Indentures (and any amendments or supplements we may enter into from time to time which are permitted under each Indenture) and the debt securities, including the definitions therein of certain terms.

General

Unless otherwise specified in a prospectus supplement, the debt securities will be direct secured or unsecured obligations of our company. The senior debt securities will rank equally with any of our other unsecured senior and unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment to any senior indebtedness.

We may issue debt securities from time to time in one or more series, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities under the applicable Indenture and will be equal in ranking.

Should an indenture relate to unsecured indebtedness, in the event of a bankruptcy or other liquidation event involving a distribution of assets to satisfy our outstanding indebtedness or an event of default under a loan agreement relating to secured indebtedness of our company or its subsidiaries, the holders of such secured indebtedness, if any, would be entitled to receive payment of principal and interest prior to payments on the senior indebtedness issued under an Indenture.

Prospectus Supplement

Each prospectus supplement will describe the terms relating to the specific series of debt securities being offered. These terms will include some or all of the following:

- the title of debt securities and whether they are subordinated, senior subordinated or senior debt securities;
- any limit on the aggregate principal amount of debt securities of such series;
- the percentage of the principal amount at which the debt securities of any series will be issued;
- the ability to issue additional debt securities of the same series;

Table of Contents

the purchase price for the debt securities and the denominations of the debt securities;

the specific designation of the series of debt securities being offered;

the maturity date or dates of the debt securities and the date or dates upon which the debt securities are payable and the rate or rates at which the debt securities of the series shall bear interest, if any, which may be fixed or variable, or the method by which such rate shall be determined;

the basis for calculating interest if other than 360-day year or twelve 30-day months;

the date or dates from which any interest will accrue or the method by which such date or dates will be determined;

the duration of any deferral period, including the maximum consecutive period during which interest payment periods may be extended;

whether the amount of payments of principal of (and premium, if any) or interest on the debt securities may be determined with reference to any index, formula or other method, such as one or more currencies, commodities, equity indices or other indices, and the manner of determining the amount of such payments;

the dates on which we will pay interest on the debt securities and the regular record date for determining who is entitled to the interest payable on any interest payment date;

the place or places where the principal of (and premium, if any) and interest on the debt securities will be payable, where any securities may be surrendered for registration of transfer, exchange or conversion, as applicable, and notices and demands may be delivered to or upon us pursuant to the applicable Indenture;

the rate or rates of amortization of the debt securities;

if we possess the option to do so, the periods within which and the prices at which we may redeem the debt securities, in whole or in part, pursuant to optional redemption provisions, and the other terms and conditions of any such provisions;

our obligation or discretion, if any, to redeem, repay or purchase debt securities by making periodic payments to a sinking fund or through an analogous provision or at the option of holders of the debt securities, and the period or periods within which and the price or prices at which we will redeem, repay or purchase the debt securities, in whole or in part, pursuant to such obligation, and the other terms and conditions of such obligation;

the terms and conditions, if any, regarding the option or mandatory conversion or exchange of debt securities;

the period or periods within which, the price or prices at which and the terms and conditions upon which any debt securities of the series may be redeemed, in whole or in part at our option and, if other than by a board resolution, the manner in which

any election by us to redeem the debt securities shall be evidenced;

Table of Contents

any restriction or condition on the transferability of the debt securities of a particular series;

the portion, or methods of determining the portion, of the principal amount of the debt securities which we must pay upon the acceleration of the maturity of the debt securities in connection with any event of default if other than the full principal amount;

the currency or currencies in which the debt securities will be denominated and in which principal, any premium and any interest will or may be payable or a description of any units based on or relating to a currency or currencies in which the debt securities will be denominated;

provisions, if any, granting special rights to holders of the debt securities upon the occurrence of specified events;

any deletions from, modifications of or additions to the events of default or our covenants with respect to the applicable series of debt securities, and whether or not such events of default or covenants are consistent with those contained in the applicable Indenture;

any limitation on our ability to incur debt, redeem stock, sell our assets or other restrictions;

the application, if any, of the terms of the applicable Indenture relating to defeasance and covenant defeasance (which terms are described below) to the debt securities;

what subordination provisions will apply to the debt securities;

the terms, if any, upon which the holders may convert or exchange the debt securities into or for our common stock, preferred stock or other securities or property;

whether we are issuing the debt securities in whole or in part in global form;

any change in the right of the trustee or the requisite holders of debt securities to declare the principal amount thereof due and payable because of an event of default;

the depositary for global or certificated debt securities, if any;

any material federal income tax consequences applicable to the debt securities, including any debt securities denominated and made payable, as described in the prospectus supplements, in foreign currencies, or units based on or related to foreign currencies;

any right we may have to satisfy, discharge and defease our obligations under the debt securities, or terminate or eliminate restrictive covenants or events of default in the Indentures, by depositing money or U.S. government obligations with the trustee of the Indentures;

the names of any trustees, depositories, authenticating or paying agents, transfer agents or registrars or other agents with respect to the debt securities;

to whom any interest on any debt security shall be payable, if other than the person in whose name the security is registered, on the record date for such interest, the extent to which, or the manner in which, any interest payable on a temporary global debt security will be paid if other than in the manner provided in the applicable Indenture;

Table of Contents

if the principal of or any premium or interest on any debt securities is to be payable in one or more currencies or currency units other than as stated, the currency, currencies or currency units in which it shall be paid and the periods within and terms and conditions upon which such election is to be made and the amounts payable (or the manner in which such amount shall be determined);

the portion of the principal amount of any debt securities which shall be payable upon declaration of acceleration of the maturity of the debt securities pursuant to the applicable Indenture if other than the entire principal amount;

if the principal amount payable at the stated maturity of any debt security of the series will not be determinable as of any one or more dates prior to the stated maturity, the amount which shall be deemed to be the principal amount of such debt securities as of any such date for any purpose, including the principal amount thereof which shall be due and payable upon any maturity other than the stated maturity or which shall be deemed to be outstanding as of any date prior to the stated maturity (or, in any such case, the manner in which such amount deemed to be the principal amount shall be determined); and

any other specific terms of the debt securities, including any modifications to the events of default under the debt securities and any other terms which may be required by or advisable under applicable laws or regulations.

Unless otherwise specified in the applicable prospectus supplement, the debt securities will not be listed on any securities exchange. Holders of the debt securities may present registered debt securities for exchange or transfer in the manner described in the applicable prospectus supplement. Except as limited by the applicable Indenture, we will provide these services without charge, other than any tax or other governmental charge payable in connection with the exchange or transfer.

Debt securities may bear interest at a fixed rate or a variable rate as specified in the prospectus supplement. In addition, if specified in the prospectus supplement, we may sell debt securities bearing no interest or interest at a rate that at the time of issuance is below the prevailing market rate, or at a discount below their stated principal amount. We will describe in the applicable prospectus supplement any special federal income tax considerations applicable to these discounted debt securities.

We may issue debt securities with the principal amount payable on any principal payment date, or the amount of interest payable on any interest payment date, to be determined by referring to one or more currency exchange rates, commodity prices, equity indices or other factors. Holders of such debt securities may receive a principal amount on any principal payment date, or interest payments on any interest payment date, that are greater or less than the amount of principal or interest otherwise payable on such dates, depending upon the value on such dates of applicable currency, commodity, equity index or other factors. The applicable prospectus supplement will contain information as to how we will determine the amount of principal or interest payable on any date, as well as the currencies, commodities, equity indices or other factors to which the amount payable on that date relates and certain additional tax considerations.

Table of Contents

Rights

We may issue rights to purchase our securities. The rights may or may not be transferable by the persons purchasing or receiving the rights. In connection with any rights offering, we may enter into a standby underwriting or other arrangement with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering. Each series of rights will be issued under a separate rights agent agreement to be entered into between us and one or more banks, trust companies or other financial institutions, as rights agent, that we will name in the applicable prospectus supplement. The rights agent will act solely as our agent in connection with the rights and will not assume any obligation or relationship of agency or trust for or with any holders of rights certificates or beneficial owners of rights.

The prospectus supplement relating to any rights that we offer will include specific terms relating to the offering, including, among other matters:

- the date of determining the security holders entitled to the rights distribution;
- the aggregate number of rights issued and the aggregate amount of securities purchasable upon exercise of the rights;
- the exercise price;
- the conditions to completion of the rights offering;
- the date on which the right to exercise the rights will commence and the date on which the rights will expire; and
- any applicable federal income tax considerations.

Each right would entitle the holder of the rights to purchase for cash the principal amount of securities at the exercise price set forth in the applicable prospectus supplement. Rights may be exercised at any time up to the close of business on the expiration date for the rights provided in the applicable prospectus supplement. After the close of business on the expiration date, all unexercised rights will become void.

If less than all of the rights issued in any rights offering are exercised, we may offer any unsubscribed securities directly to persons other than our security holders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby arrangements, as described in the applicable prospectus supplement.

Transfer Agent and Registrar

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock.

Listing

Our common stock is quoted on the Nasdaq Capital Market under the trading symbol BDSI.

Table of Contents

PLAN OF DISTRIBUTION

Pursuant to General Instruction I.B.6 of Form S-3, we are permitted to utilize the registration statement of which this prospectus forms a part to sell a maximum amount of securities equal to one-third (33.33%) of the aggregate market value our outstanding, publicly held voting and non-voting common equity in any 12 month period. We may, from time to time, offer the securities registered hereby up to this maximum amount.

We may sell the securities offered through this prospectus: (i) to or through underwriters or dealers, (ii) directly to purchasers, including our affiliates, (iii) through agents, or (iv) through a combination of any these methods or any other permissible method. The securities may be distributed at a fixed price or prices, which may be changed, market prices prevailing at the time of sale, prices related to the prevailing market prices, or negotiated prices. The prospectus supplement used for any offering an sale of securities contemplated hereunder will include the following information:

- the terms of the offering;
- the names of any underwriters or agents;
- the name or names of any managing underwriter or underwriters;
- the purchase price of the securities;
- the net proceeds from the sale of the securities;
- any delayed delivery arrangements;
- any underwriting discounts, commissions and other items constituting underwriters compensation;
- any initial public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any commissions paid to agents.

Sale Through Underwriters or Dealers

If underwriters are used in the sale, the underwriters will acquire the securities for their own account, including through underwriting, purchase, security lending or repurchase agreements with us. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions. Underwriters may sell the securities in order to facilitate transactions in any of our other securities (described in this prospectus or otherwise), including other public or private transactions and short sales. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless otherwise indicated in the prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. The underwriters may change from time to time any initial public offering price and any discounts or concessions allowed or reallowed or paid to

dealers.

Table of Contents

If dealers are used in the sale of securities offered through this prospectus, we will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale. The prospectus supplement will include the names of the dealers and the terms of the transaction.

Direct Sales and Sales Through Agents

We may sell the securities offered through this prospectus directly. In this case, no underwriters or agents would be involved. Such securities may also be sold through agents designated from time to time. The prospectus supplement will name any agent involved in the offer or sale of the offered securities and will describe any commissions payable to the agent. Unless otherwise indicated in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. The terms of any such sales will be described in the prospectus supplement.

Delayed Delivery Contracts

If the prospectus supplement indicates, we may authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase securities at the public offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. The contracts would be subject only to those conditions described in the prospectus supplement. The applicable prospectus supplement will describe the commission payable for solicitation of those contracts.

Market Making, Stabilization and Other Transactions

Unless the applicable prospectus supplement states otherwise, each series of offered securities will be a new issue and will have no established trading market. We may elect to list any series of offered securities on an exchange. Any underwriters that we use in the sale of offered securities may make a market in such securities, but may discontinue such market making at any time without notice. Therefore, we cannot assure you that the securities will have a liquid trading market.

Any underwriter may also engage in stabilizing transactions, syndicate covering transactions and penalty bids in accordance with Rule 104 under the Exchange Act. Stabilizing transactions involve bids to purchase the underlying security in the open market for the purpose of pegging, fixing or maintaining the price of the securities. Syndicate covering transactions involve purchases of the securities in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the securities to be higher than it would be in the absence of the transactions. The underwriters may, if they commence these transactions, discontinue them at any time.

Table of Contents

Derivative Transactions and Hedging

We, the underwriters or other agents may engage in derivative transactions involving the securities. These derivatives may consist of short sale transactions and other hedging activities. The underwriters or agents may acquire a long or short position in the securities, hold or resell securities acquired and purchase options or futures on the securities and other derivative instruments with returns linked to or related to changes in the price of the securities. In order to facilitate these derivative transactions, we may enter into security lending or repurchase agreements with the underwriters or agents. The underwriters or agents may effect the derivative transactions through sales of the securities to the public, including short sales, or by lending the securities in order to facilitate short sale transactions by others. The underwriters or agents may also use the securities purchased or borrowed from us or others (or, in the case of derivatives, securities received from us in settlement of those derivatives) to directly or indirectly settle sales of the securities or close out any related open borrowings of the securities.

Electronic Auctions

We may also make sales through the Internet or through other electronic means. Since we may from time to time elect to offer securities directly to the public, with or without the involvement of agents, underwriters or dealers, utilizing the Internet or other forms of electronic bidding or ordering systems for the pricing and allocation of such securities, you will want to pay particular attention to the description of that system we will provide in a prospectus supplement.

Such electronic system may allow bidders to directly participate, through electronic access to an auction site, by submitting conditional offers to buy that are subject to acceptance by us, and which may directly affect the price or other terms and conditions at which such securities are sold. These bidding or ordering systems may present to each bidder, on a so-called real-time basis, relevant information to assist in making a bid, such as the clearing spread at which the offering would be sold, based on the bids submitted, and whether a bidder s individual bids would be accepted, prorated or rejected. For example, in the case of debt security, the clearing spread could be indicated as a number of basis points above an index treasury note. Of course, many pricing methods can and may also be used.

Upon completion of such an electronic auction process, securities will be allocated based on prices bid, terms of bid or other factors. The final offering price at which securities would be sold and the allocation of securities among bidders would be based in whole or in part on the results of the Internet or other electronic bidding process or auction.

General Information

Agents, underwriters, and dealers may be entitled, under agreements entered into with us, to indemnification by us against certain liabilities, including liabilities under the Securities Act. Our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with or perform services for us, in the ordinary course of business.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York.

Table of Contents

EXPERTS

The consolidated financial statements as of and for each of the two years in the period ended December 31, 2010, incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2010, have been audited by Cherry, Bekaert & Holland, L.L.P., as stated in their report incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

All documents filed by the registrant after the date of filing the initial registration statement on Form S-3 of which this prospectus forms a part and prior to the effectiveness of such registration statement pursuant to Section 13(a), 13(c), 14 and 15(d) of the Exchange Act shall be deemed to be incorporated by reference into this prospectus and to be part hereof from the date of filing of such documents. In addition, the documents we are incorporating by reference as of the date hereof are as follows:

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed on March 11, 2011;

2. Our Current Report on Form 8-K, filed on March 16, 2011;

3. Our Current Report on Form 8-K, filed on March 21, 2011;

4. Our Current Report on Form 8-K, filed on April 5, 2011;

5. Our Current Report on Form 8-K, filed on May 13, 2011;

6. Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011, filed on May 13, 2011;

7. Our Current Report on Form 8-K/A, filed May 17, 2011;

8. Our Definitive Proxy Statement on Schedule 14A, filed June 6, 2011, and supplemental proxy materials filed on June 29, 2011;

9. Our Current Report on Form 8-K, filed June 3, 2011;

10. Our Current Report on Form 8-K, filed July 25, 2011;

11. Our Current Report on Form 8-K, filed July 26, 2011;

12. Our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011, filed on August 15, 2011;

13. Our Current Report on Form 8-K, filed August 22, 2011;

14. Our Current Report on Form 8-K, filed September 6, 2011;

15. Our Current Report on Form 8-K, filed September 30, 2011;

16. Our Current Report on Form 8-K, filed October 25, 2011;

17. Our Current Report on Form 8-K, filed November 7, 2011;

18. Our Current Report on Form 8-K, filed November 10, 2011;

Table of Contents

19. Our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2011, filed on November 14, 2011;

20. Our Current Report on Form 8-K, filed November 14, 2011;

21. Our Current Report on Form 8-K, filed November 28, 2011;

22. Our Current Report on Form 8-K, filed December 21, 2011;

23. Our Current Report on Form 8-K, filed December 30, 2011;

24. Our Current Report on Form 8-K, filed January 11, 2012;

25. The description of our common stock contained in our registration statement on Form 8-A filed on June 19, 2002, as amended June 20, 2002, and as it may be further amended from time to time; and

26. All documents that we filed with the SEC pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this registration statement by reference and to be a part hereof from the date of filing of such documents.

Any statement contained in a document we incorporate by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus (or in any other document that is subsequently filed with the SEC and incorporated by reference) modifies or is contrary to that previous statement. Any statement so modified or superseded will not be deemed a part of this prospectus except as so modified or superseded.

You may request a copy of these filings at no cost (other than exhibits unless such exhibits are specifically incorporated by reference) by writing or telephoning us at the following address and telephone number:

BioDelivery Sciences International, Inc.

324 South Hyde Park Avenue, Suite 350

Tampa FL 33606

Telephone: (813) 864-2562

Attention: James A. McNulty

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front page of those documents.

Table of Contents

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered by this prospectus. This prospectus is part of that registration statement and does not contain all the information included in the registration statement.

For further information with respect to our common stock and us, you should refer to the registration statement, its exhibits and the material incorporated by reference therein. Portions of the exhibits have been omitted as permitted by the rules and regulations of the Securities and Exchange Commission. Statements made in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as an exhibit to the registration statement, and these statements are hereby qualified in their entirety by reference to the contract or document.

The registration statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission s Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and may also be obtained from the web site that the Securities and Exchange Commission maintains at http://www.sec.gov. You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission s public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

DISCLOSURE OF COMMISSION POSITION ON

INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our certificate of incorporation, as amended, provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted under the Delaware General Corporation Law, provided that they acted in good faith and that they reasoned their conduct or action was in, or not opposed to, the best interest of our company.

Our Amended and Restated Bylaws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the Delaware General Corporation Law. Further, we maintain officer and director liability insurance.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

Table of Contents

You should rely only on the information contained in this prospectus. We have not authorized any dealer, broker, salesperson or any other person to provide you with information or to make any representations different from those contained in this prospectus or incorporated herein by reference. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the shares. This prospectus does not constitute an offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorized or in which the person making such offer is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

$40,000,000

Common Stock **Preferred Stock**
Debt Securities **Warrants**
Rights **Units**

PROSPECTUS

_____, 2012

Table of Contents

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth estimated expenses expected to be incurred in connection with the issuance and distribution of the securities being registered. All such expenses will be paid by us. The amounts listed below are estimates subject to future contingencies.

Securities and Exchange Commission Registration Fee	$4,584.00[1]
Legal Fees and Expenses	$35,000.00
Accounting Fees and Expenses	$4,500.00
FINRA Filing Fee	$4,500.00
TOTAL	$48,584.00

(1) $1,572 was previous paid in connection with Prior Registration Statement, as described in footnote 10 to the Calculation of Registration Fee table.

Item 15. Indemnification of Directors and Officers.

Our certificate of incorporation provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted under the Delaware General Corporation Law, provided that they acted in good faith and that they reasoned their conduct or action was in, or not opposed to, the best interest of our company.

Our Amended and Restated Bylaws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the Delaware General Corporation Law. Further, we maintain officer and director liability insurance.

Item 16. Exhibits.

The following exhibits are filed with this Registration statement.

Exhibit

Number	**Description of Document**
4.1	Form of Indenture[1]
4.2	Form of Debt Securities[1]
4.3	Form of Warrant Agreement, if any, including form of Warrant[1]
4.4	Form of Preferred Stock Certificate[1]
4.5	Form of Right Certificate [1]
4.6	Registrant s Amended and Restated 2001 Stock Incentive Plan[2]
4.7	Registrant s 2011 Equity Incentive Plan[3]
5.1	Opinion of Ellenoff Grossman & Schole LLP*
23.1	Consent of Cherry, Bekaert & Holland, L.L.P.*
23.2	Consent of Ellenoff Grossman & Schole LLP (included in Exhibit 5.1)*
24.1	Power of Attorney (included in Part II of this Registration Statement)*
25.1	Statement of Eligibility of trustee on Form T-1+

* Filed herewith.

\+ To be filed pursuant to Rule 305(b)(2) of the Trust Indenture Act.

(1) If applicable, to be filed by amendment or by a report filed under the Exchange Act, and incorporated herein by reference.

(2) Filed as part of the Company s Form SB-2, Amendment No. 2 on February 1, 2002.

(3) Filed as part of the Company s 2011 Schedule 14A on July 13, 2011.

Table of Contents

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; *provided, however*, that paragraphs (a)(1)(i) and (a)(1)(ii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B,

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the

Table of Contents

information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided*, *however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to the effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer and sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an

Table of Contents

employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding), is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(e) The undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the SEC under Section 305(b)(2) of the Trust Indenture Act.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Raleigh, State of North Carolina, on January 31, 2012.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer

BioDelivery Sciences International, Inc. and each of the undersigned do hereby appoint Mark A. Sirgo and James A. McNulty and each of them severally, its or his true and lawful attorney to execute on behalf of BioDelivery Sciences International, Inc. and the undersigned any and all amendments to this Registration Statement on Form S-3 and to file the same with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission; each of such persons shall have the power to act hereunder with or without the other.

In accordance with the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates stated.

Person	Capacity	Date
/s/ Francis E. O Donnell, Jr.	Executive Chairman	January 31, 2012
Francis E. O Donnell, Jr.		
/s/ Mark A. Sirgo	President and Chief Executive Officer	January 31, 2012
Mark A. Sirgo	(Principal Executive Officer)	
/s/ James A. McNulty	Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)	January 31, 2012
James A. McNulty		
/s/ William B. Stone	Lead Director	January 31, 2012
William B. Stone		
/s/ John J. Shea	Director	January 31, 2012
John J. Shea		
/s/ William S. Poole	Director	January 31, 2012
William S. Poole		
/s/ Samuel P. Sears, Jr.	Director	January 31, 2012
Samuel P. Sears, Jr.		